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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,640	04/09/2004	Mark A. Holland	4010.3002 US1	9018

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EXAMINER	
KINSEY, NICOLE	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,640	HOLLAND ET AL.	
	Examiner	Art Unit	
	Nicole E. Kinsey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/12/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

For the Election/Restriction below, it is assumed that claim 6 contains a typographical error and should read ATCC# PTA-5075 instead of ATCC# PTA-5057 and that claim 48 is intended to be a composition because it depends from claim 47, which is drawn to a composition.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 23-24, 36-40, 47-52, 55 and 56, drawn to a bacteriophage, a composition/formulation comprising the bacteriophage and kits, classified in class 435, subclass 235.1.

II. Claims 7-10, drawn to a method of purifying a bacteriophage, which is lytic for Methylobacteria, classified in class 435, subclass 235.1 and class 435, subclass 252.1.

III. Claims 11-12, drawn to a method of purifying a bacteriophage, which is lytic for HBB, classified in class 435, subclass 235.1 and class 435, subclass 252.1.

IV. Claims 13-22, drawn to a method of removing Methylobacteria from a plant using a bacteriophage, a method of producing male sterility in a plant using a bacteriophage and a method of obtaining hybrid seeds of a plant

using a bacteriophage, classified in class 435, subclass 235.1 and class 435, subclass 252.1.

V. Claims 25-35, drawn to a method of treating a Methylobacteria or HBB infection in a patient and a method of treating an HBB associated autoimmune disease in a patient using a bacteriophage, classified in class 435, subclass 235.1 and class 435, subclass 252.1.

VI. Claims 41-46, drawn to a method of disinfecting an environmental surface contaminated with Methylobacteria or HBB using a bacteriophage, classified in class 435, subclass 235.1 and class 435, subclass 252.1.

VII. Claims 53-54, drawn to a method of making a medicament containing a bacteriophage, classified in class 435, subclass 235.1.

The inventions of Group I and Groups II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the claimed method, i.e., obtaining bacteriophage from a sample, plating the bacteriophage with a host bacteria, collecting plaques, and purifying the plaques, can be used to produce other types of bacteriophage, e.g., lambda phage.

In addition to their distinctness, searching the inventions of Groups I to III would impose a serious search burden. While the Groups can be identically classified under

U.S. Patent Classification guidelines, to search them together would present a search burden on the Examiner because the search required for Group I is not required for either of Groups II and III and vice versa. Thus, a separate search is required for each Group, which would present a search burden on the Examiner. Therefore, because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The inventions of Group I and Groups IV-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case antibiotics against Methylobacteria (and HBB) can be used to remove Methylobacteria from a plant, to produce male-sterile plants by reducing or eliminating the presence of Methylobacteria on the plant, to obtain hybrid seeds of a plant, to treat patients, and to disinfect a surface.

In addition to their distinctness, searching the inventions of Group I and Groups IV-VII would impose a serious search burden. While the Groups can be identically classified under U.S. Patent Classification guidelines, to search them together would present a search burden on the Examiner because the search required for Group I is not required for any of Groups IV-VII and vice versa. Thus, a separate search is

required for each Group, which would present a search burden on the Examiner. Therefore, because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The inventions of Groups II-VII are drawn to independent and distinct methods, which differ in the method objectives, method steps, in the reagents used, and have different final outcomes. Group II, which is drawn to a method of purifying a bacteriophage, which is lytic for Methylobacteria, requires plating and infecting Methylobacteria with a bacteriophage. Group III, which is drawn to a method of purifying a bacteriophage, which is lytic for HBB, requires plating and infecting HBB with a bacteriophage. Group IV, which is drawn to a method of removing Methylobacteria from a plant, a method of producing male sterility in a plant, and a method of obtaining hybrid seeds of a plant, requires contacting a plant or seed with a bacteriophage. Group V, which is drawn to a method of treating a Methylobacteria or HBB infection in a patient and a method of treating an HBB associated autoimmune disease in a patient, requires administering a bacteriophage to a patient. Group VI, which is drawn to a method of disinfecting an environmental surface contaminated with Methylobacteria or HBB, requires contacting a surface with a bacteriophage. Group VII, which is drawn to a method of making a medicament containing a bacteriophage, requires mixing a bacteriophage with other ingredients to formulate the medicament.

Thus, as noted above, the inventions of Groups II-VII each require different steps and reagents, and each Group has a different objective and final outcome. Further, the search of any one Group is not required for any other Group. Thus, a separate search is required for each Group, which would present a search burden on the Examiner. Therefore, because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on 8:00 am to 4:30 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Nicole Kinsey, PhD
Patent Examiner
Art Unit 1648

Bruce Campell

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